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IN THE

Supreme Court of the United States

OCTOBER TERM, 1966

No. 783

HENRY SCHEIN, doing business as Henry Schein,

Petitioner,

—v—

UNITED STATES OF AMERICA,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Second Circuit, entered in the above-entitled case on October 21, 1966.

Citations to Opinions Below

The opinion of the District Court (A. 100a)* printed in Appendix C hereto, *infra* p. App. C1, has not been reported as yet. The opinion of the United States Court of Appeals for the Second Circuit, printed in Appendix B hereto, *infra* p. App. B1, has also not been reported as yet. Petitioner's application to stay the mandate of the Circuit Court was granted by that Court on November 15, 1966.

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* References with the prefix "A" are to petitioner's appendix filed with the Circuit Court of Appeals. The Government did not file an appendix.

Jurisdiction

The judgment of the Circuit Court of Appeals entered on October 21, 1966, is printed in Appendix D hereto, *infra* p. App. D1. The jurisdiction of this court is invoked under 28 U.S.C. Section 1254(1).

Questions Presented

1. Can a defendant who has committed no crime but who has pleaded guilty to charges of regulatory offenses for which a lack of criminal intent is irrelevant, be sent to prison without review of by the Circuit Court of the legal sufficiency of those charges on the ground that his plea of guilty and subsequent sentence conclusively bars all later challenges to the legal sufficiency of the charges, absent an exercise of the district court's discretion granting him leave to withdraw that plea?

2. A Food and Drug inspector who misrepresented himself as a physician ordered prescription drugs from petitioner's firm which thereupon labeled them appropriately for delivery to a physician and filled the order. On these facts, admitted by the Government, a criminal charge of misbranding was made, under §§352(f)(1) and 353(b)(1) of the Federal Food, Drug and Cosmetics Act.

(a) Can such charges stand when applicable regulations governing labeling contain explicit provisions exempting from the requirement in issue here, adequate directions for use by laymen, not only shipments to physicians but also shipments or deliveries to law

enforcement officials and employees of such agencies as the F.D.A.?

(b) May a wholesale sale in regular course to an F.D.A. inspector posing as a physician be deemed "dispensing without a prescription" in violation of all commonly understood as well as technical meanings of the term "dispensing"?

3. Where petitioner had no criminal record but did have a civil litigation record involving administrative agencies, in which the agencies had not been upheld by the courts, and had otherwise received infrequently administrative directions not uncommon in the industry, which he had obeyed, but the record of sentencing shows that he was erroneously deemed to have a "long record of illegal activities," that he was erroneously singled out as one unique for having these problems with the regulatory agencies, and that the sentencing judge treated his lawyer's travel to Washington, D.C., made in an effort to work out petitioner's differences with the F.D.A., as itself evidence that petitioner was a wrongdoer, may petitioner obtain review of his sentencing under *Townsend* v. *Burke*, 334 U.S. 736 (1948)?

Statutes, Regulations and Rules Involved

Statutes involved are 21 U.S.C., Sections 352(f), 353(b)(1), 331(a), 333(a) and 333(c). These are printed in Appendix A, *infra*, pp. App. 1 to App. 8. Regulations involved are those promulgated under Section 352(f), i.e., 21 C.F.R. Section 1.106 (a), (b) and (m). Rules involved are Rules 12 and 32(d) of the Federal Rules of Criminal Procedure.

Statement

This is a federal criminal case, arising under the Food, Drug and Cosmetics Act, which was originally brought by an information filed in the United States District Court for the Eastern District of New York on August 26, 1964. A judgment of conviction was entered in that court on March 17, 1966, following petitioner's plea of guilty to counts 3 and 4 of the information. After a sentence of two months imprisonment had been imposed there was a change of counsel and a motion was brought by new counsel, alleging that the counts to which petitioner had pleaded guilty failed to charge a crime. Relief of two sorts was sought, dismissal of the counts and leave to withdraw the plea of guilty. The District Court (Rayfiel, *J.*) denied both (A. 100a-105a). This order was entered on June 8, 1966, and on that same day petitioner filed his notice of appeal.

On October 21, 1966 argument was heard by the United States Court of Appeals for the Second Circuit. At the conclusion of the argument the Court announced through Judge Waterman that the judgment was affirmed as lying within the discretion of the District Court. The judgment of the Court of Appeals was thereupon entered on October 21, 1966. The opinion does not repeat Judge Waterman's statement but is consistent with it. The merits of the legal insufficiency point raised by petitioner were not discussed therein.

The essential facts underlying the counts in question are uncontroverted, and admitted by the Government's

own bill of particulars, Counts 3 and 4 of the information (A. 6a-7a) charged that on or about the 31st day of January, 1963 the defendant "caused to be introduced, introduced, caused to be delivered and delivered for introduction into interstate commerce, from Flushing, New York" (the place where Mr. Schein's business was located) "to Howard E. Pilson, San Francisco, California", certain prescription drugs, Sodium Pentobarbital (count 3) and Procaine Penicillin G in Aqueous Suspension (count 4).

In its bill of particulars the Government alleged: "Item 1. Howard E. Pilson, at the times mentioned in the information, was an Inspector in the Food and Drug Administration. Item 4. Howard E. Pilson represented himself as an M.D."

Petitioner, who is the proprietor of a large wholesale drug house, which for some twenty years has specialized in wholesale distribution by mail to physicians, dentists, hospitals, clinics, pharmacies and governmental agencies throughout the country (A. 33a-36a; 69a), has made no denial of the charge that Inspector Pilson's order was filled; nor did he deny that the order was labeled for shipment to a doctor. Petitioner had given instructions to his employees to check orders from physicians against medical and similar directories so as to prevent laymen from receiving prescription drugs. Hundreds of such checks have been made and a large number of persons have been refused shipment (A. 37a-43a). In this case a clerical error led to the shipment to Pilson of the prescription drugs which were the subject of counts 3 and 4 of the information.

The charges made by these counts were that the drugs sent to Pilson were misbranded, because the labeling on them lacked adequate directions for use by laymen, in violation of 21 U.S.C. §352(f)(1), and constituted illegal dispensing, within the meaning of 21 U.S.C. §353(b)(1). The introduction of misbranded drugs into interstate commerce is prohibited under 21 U.S.C. §331(a), and criminal penalties therefor are provided under 21 U.S.C. §333(a).

Labeling

The attack made on these charges of misbranding rests on the plain meaning of applicable regulations which define the requirements for labeling. §352(f), the section relied on by the Government, reads as follows:

> §352. A drug or device shall be deemed to be misbranded— . . .
>
> (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in which manner and form, as are necessary for the protection of users: *Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.*" (Emphasis added.)

The phrase "adequate directions for use" means use by laymen. 21 C.F.R. §1.106(a) provides: "Drugs and devices; directions for use—(a) Adequate directions for use. 'Adequate directions for use' means directions under which the layman can use a drug or device safely and for the purposes for which it is intended." 21 C.F.R. §1.106(a).

Under the bald statute all drugs must be labeled for use by laymen, even drugs shipped to physicians, hospitals, testing laboratories and the like. It is only under the exemptions of the regulations that labeling for these recipients need not contain "adequate directions for use", i.e., directions for laymen.

Regulations specifically exempt shipments to physicians, the person Pilson purported to be, and to persons such as he was, those engaged in law enforcement, as well as employees of an agency such as the F.D.A.

> "(b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503(b)(1) of the act (21 U.S.C. §353(b)(1)) [i.e., a prescription drug] shall be exempt from section 502 (f)(1) (21 U.S.C. §352(f)(1)) [the labeling requirement of adequate directions for use by laymen] if all the following conditions are met:
>
> "*The drug is:*
>
> (i)(a) *In the possession of a person (or his agents or employees) regularly and lawfully engaged in the* manufacture, *transportation, storage,* or wholesale distribution *of prescription drugs; or*
>
> (b) *In the possession of* a retail hospital, or clinic pharmacy, or *a public health agency, regu-*

larly and lawfully engaged in dispensing prescription drugs; or

(c) *In the possession of a practitioner licensed by law to administer or prescribe such drugs;*" (Emphasis added.)

The regulation then goes on to specify labeling requirements appropriate for shipments to physicians, which were the requirements complied with in the Pilson shipment, rather than the requirement of adequate directions for use by laymen.

21 C.F.R. §1.106(m) moreover, provides:

"(m) *Exemption for drugs and devices for use in* teaching, *law enforcement,* research, and analysis. *A drug or device subject to paragraph (b)* [prescription drugs], (c), or (d) *of this section shall be exempt from section 352 (f)(1) of the act* [the labeling requirement] *if shipped or sold to, or in the possession of, persons regularly and lawfully* engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or *engaged in law enforcement,* or in research not involving clinical use, or in chemical analysis, or physical testing, *and is to be used only in such* instruction, *law enforcement,* research, analysis or testing." (Emphasis added)

Pilson was a person regularly and lawfully engaged in law enforcement. He was an employee of the F.D.A., which regularly and lawfully engaged in transportation and storage of prescription drugs, and is a public health agency regularly and lawfully engaged in dispensing prescription drugs. This was

admitted in the Government's brief filed in the Circuit Court (p. 17). The plain language of the applicable regulations thus say that there was nothing wrong with the labeling on the shipments to Pilson. These exemptions are unmistakably stated and rest on a sound foundation of reason. A requirement of this sort, imposed on sellers or shippers regardless of consciousness of wrongdoing, should apply only to sales or shipments made to laymen. Howard E. Pilson was not a layman, and he did not pose as a layman. The shipment was not improperly labeled for the person he was, or for the person he held himself out to be.

Dispensing

As to "dispensing without a prescription from a practitioner licensed by law to administer such drug," (A. 6a-7a), the other part of the misbranding charge, such a charge makes no sense in the circumstances of this case.

Dorland's Illustrated Medical Dictionary (24 ed., 1965) defines "dispense":

> "To prepare and distribute medicines to those who are to use them."

Similar definitions appear in the Prescription Pharmacy (Sprowls, editor, 1963); Ballantine's Law Dictionary (1948); Webster's New International Dictionary (2d ed.), definition 6; and Black's Law Dictionary (4th ed.). It is not dispensing to deliver medicines to a physician, or to an F.D.A. inspector posing as a physician.

In addition to dictionary definitions one must turn to the purposes of the statute. 21 U.S.C. §353(b) prohibits certain kinds of transactions, referred to as "dispensing", unless a physician has written a prescription.

Thus, if a physician or retail pharmacist gives a drug to a layman this is dispensing. Supervision by the physician, as through a prescription, is clearly required, and delivery without it is illegal.

If the physician or retail pharmacist orders and receives drugs from a manufacturer or distributor this is clearly not dispensing by either the shipper or the recipient. No patient is involved, and there is no one for whom to prescribe. The drugs must be able to move in commerce for them to be available to consumers. Prescriptions do not and cannot be utilized in such transactions, which occur by the thousands in ordinary trade. Such prescriptions would make no sense.

Nor would it be fair, by such twisting of language, to make criminal such conduct as had always been considered legal by the pharmaceutical industry, and by the community in general. Such charges fail to give adequate notice of what conduct is prohibited, and violate due process. See *Winters* v. *New York*, 333 U.S. 507 (1948). If this is dispensing then most of the daily commerce of the drug industry is illegal, and the only cure is an absurd one, "prescriptions" to accompany all purchase orders, or even intra-company shipments.

The Sentencing

Petitioner had never been arrested or convicted of a crime, was a man of 58, a registered pharmacist for 38 years, a family man with two grown sons, one a pharmacist and the other a recent law graduate, and winner of the Jamaica Jewish Center "Man of the Year" award for 1965. Despite this clean record and despite the fact that the normal sentence in a case of this sort would have been a fine, the lower court sentenced Mr. Schein to two months in prison.

The explanation of this prison term, short in duration but monstrous in its human consequences, can be seen in the lower court's remarks during sentencing, through which filtered traces of a highly partisan F.D.A. report on civil litigation and administrative history, none of which was criminal or anti-social. The sentencing judge admitted that he had acted on such a report, which he deemed the "record", but at first refused to disclose its contents. Only later, on a motion to reduce sentence, was it partly disclosed, and even then no real opportunity was given to challenge partisan allegations, hearsay and innuendo or to explain facts or put them into context.

The court stated: *"my record shows—and there is no question about the authenticity of the record—that he has a very, very long record of illegal activities similar to those involved in the case here,* running over a period of long—a long period of time. He has had repeated warnings to discontinue." (Emphasis added.) (A. 10a-11a).

The Court refused to disclose what these allegedly illegal activities had been, even when explicitly requested by the defendant to do so.

> "The Defendant: May I hear some of these, please?
>
> "The Court: No. This is upon the official record. This is a part of the official record." (A. 11a).

Not only would the defendant not be told about these charges, but the hearsay pre-sentence report had now become "the official record". Yet palpably there was no list of convictions and the civil record was demonstrably neither criminal nor anti-social. (See Statement of Facts in petitioner's brief in the Circuit Court, pp. 11-21, and the underlying documents cited therein which are part of the certified record.)

Counsel attempted to guess at the Court's meaning, and suggested the disagreements which Mr. Schein had had with the F.D.A. The Court's answer was astounding.

> "Mr. Sheldon: Your Honor, may I say this. Your Honor, at this point, I have been with this man for over 30 years myself. I know what the Government has accused him of. I challenge the Government to point it out to us. I say this, and I say it very emphatically, that it is not so. The Government has taken one point of view, and I have been in Washington on this and discussed it with the higher officials there. They have taken a view that certain things are not permissible.

"The Court: *What occasion was there to go to Washington unless there was something wrong?*" (Emphasis added.) (A. 11a-12a).

The Court then went on to make clearly erroneous statements that singled out appellant's firm as one unique for misbranding problems.

"The Court: . . . The fact is that Abbott and Parke-Davis and Sharp & Dohme, and all of the others, they don't have this problem.

"Mr. Sheldon: Yes, they have.

"The Court: Well, they don't have them in our court." (A. 14a)

A report submitted by the F.D.A. to the Fountain Subcommittee (A. 29a) shows that the F.D.A. has charged these firms and many other large drug houses with numerous serious misbranding violations. There were some eight such violations for Merck, Sharp & Dohme on the list submitted, over eleven for E. R. Squibb and some for all the other firms named by the judge here. These cases indeed were not the subject of criminal prosecution and were apparently uncovered in ways other than through the elaborate hoax used against petitioner. This shows only greater clemency by the F.D.A. for these firms, not greater care by the firms. The F.D.A. report to the Fountain Subcommittee, moreover, was ignored by the sentencing judge, even after petitioner's attorneys had submitted it to him (A. 95a).

The seriousness of this situation becomes apparent when one considers the generality of its application. Here is a man who had the boldness to stand up to

arbitrary administrative actions, to go to court with the agencies and to beat them. He has also had the courage to stand up against great industry resentment, based on his firm's price discounting. Because the elaborate trap of Inspector Pilson was set for this firm, the criminal law should not be used to take reprisals through the medium of a secret and unchallenged presentence report. A man should not be punished criminally for what was not criminal. Otherwise the dissenter will be silenced, and passive acquiescence in administrative determinations will be the only safe course. Petitioner had no record; the offense if any, was due to an oversight by his employees. There was nothing here which properly called for a prison term, and the sentencing judge acted on the basis of errors and inaccuracies.

Reasons For Granting the Writ

1. The principle that a plea of guilty bars later challenges to the legal sufficiency of the charges, absent discretionary leave to withdraw that plea, is novel, extremely broad in application, and, we believe, undesirable in its consequences. Such a principle underlies the holding by the Court of Appeals here, announced by Judge Waterman in open court, that the issues in this case lay within the discretion of the District Court. It means that a man can go to prison even though he committed no crime, because the legal issues as well as the factual ones are removed by the plea of guilty, and are not restored except with leave of the District Court. It bars not only direct review but also collateral attack, which would be available here under *United States* v. *Morgan*, 346 U.S. 502

(1954). It contradicts the generally held view. See 8 Moore, Federal Practice, ¶11.04. It bars the correction of fundamental errors. Such a holding is in derogation of Rule 12, Federal Rules of Criminal Procedure, violates the concept that collateral attack is available to correct fundamental errors and, in the final analysis, permits imprisonment without due process of law.

2. The regulations involved in this case are of broad application. If they mean what they say counts 3 and 4 of the information did not charge crimes. If they do not mean what they say this is of importance to the entire pharmaceutical industry and to the agencies regulating that industry.

Clear and unmistakable notice of what conduct is proscribed is essential in a complex statutory scheme such as this, particularly where lack of intent to do wrong is no defense. As the Court of Appeals for the Fifth Circuit has put it, in speaking of the Food, Drug and Cosmetics Act and the regulations under it:

> "This seems especially necessary as to acts asserted to be criminal offenses under a statutory scheme as complex as this one and in which severe penalties of fine and imprisonment may be exacted even as misdemeanors when the actions taken or omitted are determined to have been done with no 'intent to defraud or mislead.' 21 U.S.C.A. §333 (a), (b). When, as this statute permits, innocuous and morally innocent actions may send men to jail for long periods of time because mistakes in processing or labeling, etc. result in *economic* adulteration, it is essential that the offense (or offenses) be identified and charged in terms which

adequately relate the actions to the statute." *Van Liew* v. *United States*, 321 F. 2d 664, 674 (5th Cir. 1963).

3. The sentencing procedure in the instant case raises a novel and important constitutional issue, under *Townsend* v. *Burke*, 334 U.S. 736 (1948). The question is whether a sentence can stand when it is based on materially incorrect assumptions about the defendant's record and other significant matters. In *Townsend* the defendant lacked counsel. The Court said:

> "Counsel, had any been present, would have been under a duty to prevent the court from proceeding on such false assumptions and perhaps under a duty to seek remedy elsewhere if they persisted."

Here counsel is seeking that remedy and the novel and important question here is whether it should be granted.

CONCLUSION

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted

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APPENDIX A

Statutes and Regulations Involved

Federal Food, Drug and Cosmetic Act and General Regulations.

The following acts and the causing thereof are hereby prohibited:

21 U.S.C. §331. (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

21 U.S.C. §333. (a) Any person who violates any of the provisions of section 331 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

21 U.S.C. §352. A drug or device shall be deemed to be misbranded . . .

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That

where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

21 C.F.R. §1.106 *Drugs and devices; directions for use*—(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(2) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

(3) Frequency of administration or application.

(4) Duration of administration or application.

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(6) Route or method of administration or application.

(7) Preparation for use (shaking dilution, adjustment of temperature, or other manipulation or process).

(b) *Exemption for prescription drug.* A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:

(1) The drug is:

(i) *(a)* In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or

(b) In the possession of a retail hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(c) In the possession of a practitioner licensed by law to administer or prescribe such drugs; and

(ii) It is to be dispensed in accordance with section 503(b).

(2) The label of the drug bears:

(i) The statement "Caution: Federal law prohibits dispensing without prescription"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) The quantity or proportion of each active ingredient, as well as the information required by section 502(d) and (e); and

(v) If it is for other than oral use, the names of all inactive ingredients, except that:

(a) Flavorings and perfumes may be designated as such without naming their components.

(b) Color additives may be designated as coloring without naming specific color components unless the naming of such components is required by a color additive regulation prescribed in Part 8 of this chapter.

(c) Trace amounts of harmless substances added solely for individual product identification need not be named. If it is intended for administration by parenteral injection, the quantity or proportion of all inactive ingredients, except that ingredients added to adjust the pH or to make the drug isotonic may be declared by name and a statement of their effect; and if the vehicle is water for injection it need not be named.

(vi) An identifying lot or control number from which it is possible to determine the complete manufacturing history of the package of the drug:

Provided, however, That in the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information, but which are packaged within an outer container from which they are removed for dispensing or use, the information required by subdivisions (ii), (iii) and (v) of this subparagraph may be contained in other labeling on or within the package from which it is to be dispensed, and the information referred to in sub-

division (i) of this subparagraph may be placed on such outer container only, and the information required by subdivision (vi) of this subparagraph may be on the crimp of the dispensing tube.

(3)(i) Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and

(ii) If the article is subject to section 505, 506, or 507 of the act, the labeling bearing such information is the labeling authorized by the effective new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs:

Provided, however, That the information required by subdivision (i) of this subparagraph may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a proposal to omit such information from the dispensing package under this proviso.

(4) Any labeling, as defined in section 201(m)

of the act, whether or not it is on or within a package from which the drug is to be dispensed, distributed by or on behalf of the manufacturer, packer, or distributor of the drug, that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for the use of the drug (other than dose information required by subparagraph (2)(ii) of this paragraph and paragraph (c)(2)(ii) of this section) contains:

(i) Adequate information for such use, including indications, effects, dosages, routes, methods, and frequency and duration of administration and any relevant hazards, contraindications, side effects, and precautions, under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all conditions for which it is advertised or represented; and if the article is subject to section 505, 506, or 507 of the act, the labeling providing such information is substantially the same as the labeling authorized by the effective new-drug application or required as a condition for its certification or exemption from certifications; and

(ii) The same information concerning the ingredients of the drug as appears on the label and labeling on or within the package from which the drug is to be dispensed;

Provided, however, That the information required by subdivisions (i) and (ii) of this subparagraph is not required on the so-called reminder-piece labeling which calls attention to the name of the drug but does

not include indications or dosage recommendations for use of the drug.

(5) All labeling, except labels and cartons, bearing information for use of the drug also bears the date of the issuance or the date of the latest revision of such labeling.

21 C.F.R. §1.106(m). *Exemption for drugs and devices for use in teaching, law enforcement, research, and analysis.* A drug or device subject to paragraph (b), (c), or (d) of this section shall be exempt from section 502 (f)(1) of the act if shipped or sold to, or in the possession of persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in law enforcement, or in research not involving clinical use, or in chemical analysis, or physical testing and is to be used only for such instruction, law enforcement, research, analysis, or testing.

21 U.S.C. §353(b)(1). A drug intended for use by man which—

(A) is a habit-forming drug to which section 502(d) applies; or

(B) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(C) is limited by an approved application under section 505 to use under the professional supervision of a practitioner licensed by law to administer such drug,

shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug, or (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.

Rules Involved

"Rule 12. Pleadings and motions before trial—Defenses and objections. . . .

(b) The motion raising defenses and objections. . . .

(2) Defenses and objections which must be raised. —* * * Lack of jurisdiction or the failure of the indictment or information to charge an offense shall be noticed by the court at any time during the pendency of the proceeding."

"Rule 32. Sentence and judgment . . . .

(d) Withdrawal of plea of guilty.—A motion to withdraw a plea of guilty or of nolo contendere may be made only before sentence is imposed or imposition of sentence is suspended; but to correct manifest injustice the court after sentence may set aside the judgment of conviction and permit the defendant to withdraw his plea."

APPENDIX B

Opinion of Court of Appeals for Second Circuit

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

No. 137—September Term, 1966

(Argued October 21, 1966 Decided October 21, 1966)

Docket No. 30653

UNITED STATES OF AMERICA,

Appellee,

—v—

HENRY SCHEIN, doing business as Henry Schein,

Defendant-Appellant.

Before:

WATERMAN, HAYS and ANDERSON,

Circuit Judges.

Appeal from the United States District Court for the Eastern District of New York. Affirmed.

Michael J. Walsh, Asst. U.S. Attorney, Joseph P. Hoey, U.S. Attorney, E.D.N.Y., *for Appellee.*

Sheldon H. Elsen, Lewis Shapiro, Orans, Elsen & Polstein, New York City, *for Appellant.*

PER CURIAM:

On January 21, 1966 appellant entered a plea of guilty to certain counts of an information filed against him in the United States District Court for the Eastern District of New York. He had been informed of his legal and constitutional rights. Sentence was imposed on March 17, 1966, but that day execution of sentence was stayed until March 28, then to April 28, then to May 9, and then to May 16.

While execution of sentence was thus being stayed appellant on April 14, 1966 moved for reduction of sentence, which motion was denied on May 3. On May 12 appellant moved by an order to show cause to seek leave to withdraw his guilty plea under Fed. R. Crim. P. 32(b) or to obtain a dismissal under Fed. R. Crim. P. 12(b)(2) of the counts to which he had pled guilty on the ground that the counts did not charge crimes. The appellant was admitted to bail pending decision upon this motion.

On June 8 an order was filed denying the May 12 motion, and on that day a notice of appeal was filed from that order. The appeal was argued to us today; we find no merit in it.

We have detailed the proceedings below because the Government argued that the appeal, ostensibly timely taken from the June 8 order, was in fact an untimely appeal from the judgment of conviction entered on March 17, 1966. We find it unnecessary to decide whether the appeal was or was not timely.

Appellant voluntarily pled guilty with full knowledge of the extent of possible punishment permissible under the pertinent statute. We find no merit in the claim that there has been any manifest injustice to appellant.

The conviction below and the orders of the court entered subsequently thereto are affirmed in open court.

STERRY R. WATERMAN

PAUL R. HAYS

ROBERT P. ANDERSON

U. S. C. JJ.

October 21, 1966

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APPENDIX C

Opinion of District Court

[SAME TITLE]

Appearances: ORANS, ELSEN & POLSTEIN, Esqs.
By Sheldon H. Elsen, Esq., of Counsel,
For the Motion

HON. JOSEPH P. HOEY,
United States Attorney,
By Michael J. Walsh, Esq.,
Assistant U. S. Attorney, of Counsel,
In Opposition.

RAYFIEL, J.

On August 26, 1964 a 16-count information was filed in this Court charging the defendant with the commission of violations of Sections 331(a), 333(a), 353(b)(1), 353(b)(1)B and 352(f)(1) of Title 21 of the United States Code.

The defendant, represented by counsel, was arraigned on September 24, 1964 and entered a plea of not guilty. His counsel requested and obtained a period of 30 days within which to make appropriate motions and the defendant was then released on his own recognizance to await trial.

On January 21, 1966 the defendant, again represented by counsel, withdrew his plea of not guilty, and pleaded guilty to counts 3 and 4 of said information, after having been fully informed of his legal and constitutional rights and warned of the possible conse-

quences of such a plea. He was continued on his own recognizance to await sentence on March 17, 1966. Several days in advance of that date defendant's counsel submitted to the Court voluminous copies of defendant's business records and other documents for its consideration in the imposition of sentence. On March 17, after counsel had presented many facts of a mitigating nature and the defendant had made a statement in his own behalf, the Court imposed a sentence of two months and a fine of $1,000 on each of counts 3 and 4, the prison sentences to run concurrently. Execution of the sentence was stayed until March 28, 1966. Upon motion of the United States Attorney counts 1, 2 and 5 through 16 were then dismissed.

On March 23 execution of sentence was further stayed until April 28. On April 14 the defendant filed a motion under Rule 35 of the Federal Rules of Criminal Procedure to reduce the sentence theretofore imposed "on grounds of new evidence pertaining to the background and character of the defendant. . . ." The motion was argued at considerable length by his attorney, who submitted, *inter alia,* some 75 pages of affidavits in support thereof. At the conclusion of the argument I reserved decision thereon and granted a further stay to May 9. On May 3 I denied the motion to reduce the sentence and on May 5 granted the defendant a further stay of the execution of the sentence to 4 P.M. on May 16.

By stipulation dated May 9 and filed May 11 Orans, Elsen and Polstein, Esqs., were substituted as attorneys for the defendant in place and stead of Sheldon and Tarnoff, Esqs., who had represented the defendant in all prior proceedings herein, and on May 12 the former moved

(1) under Rule 12(b)(2) of the aforementioned Rules to dismiss counts 3 and 4 of the information on the ground that they failed to charge a crime, and

(2) under Rule 32(d) for leave to withdraw his plea of guilty to correct a manifest injustice, since "[T]he defendant has good defenses to counts 3 and 4 and was misadvised by prior counsel to plead guilty to these counts in the mistaken assumption that there were no defenses thereto."

Rule 12(b)(2), supra, provides in pertinent part that the failure of the information to charge an offense shall be noticed by the court *at any time during the pendency of the proceeding.*

Rule 32(d), supra, provides that a motion to withdraw a plea of guilty may be made only before sentence is imposed, but that *"to correct manifest injustice* the court *after sentence may* set aside the judgment of conviction and permit the defendant to withdraw his plea." (Emphasis ours).

Section 331(a), supra, prohibits the introduction or delivery for introduction into interstate commerce of any drug which is misbranded, and section 333(a), supra, provides the penalty therefor. Section 352 (f)(1) provides in pertinent part that a drug shall be deemed misbranded unless the labeling bears adequate directions for use, provided, however, that where such requirement, as applied to any drug, is not necessary for the protection of the public health, the Secretary (Secretary of Health, Education and Welfare) shall promulgate regulations exempting such drug from such requirement. Section 353(b)(1)(B), so far as here pertinent, provides that a drug intended for use by man which is not safe for use except under the supervision of a practitioner licensed by law to administer such drug shall be dispensed

only upon the written prescription of such a practitioner, and that "[T]he act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale."

Pursuant to the authority vested in him the Secretary promulgated a regulation known as Section 1.106 (b) which provides in part as follows:

"(b) Exemption for prescription drugs. A drug subject to the requirements of section 503(b)(1) (353(b)(1), supra) of the act shall be exempt from section 502(f)(1) (352(f)(1), supra) if all the following conditions are met:

(1) The drug is:

(i) (a)(in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage or wholesale distribution of prescription drugs; or

(b) In the possession of a retail hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs; or

(c) In the possession of a practitioner licensed by law to administer or prescribe such drugs; and

(ii) It is to be dispensed in accordance with section 503(b) (353(b), supra)."

Howard E. Pilson, to whom the drugs referred to in counts 3 and 4 were delivered, was a government inspector who, in ordering the drugs, posed as a physician. The defendant, in support of his motion under Rule 12(b)(2) to dismiss counts 3 and 4 of the information, contends that the drugs in question, though not in the hands of a person authorized to practice medicine, within the exemption under Sec-

tion 1.106(b)(1)(c), were in the possession of a person exempted under subdivision (b)(1)(i)(a) of that Section since, as he argues in his memorandum, "[T]here can be no dispute but that the Food and Drug Administration is regularly and lawfully engaged in at least the transportation and storage of prescription drugs if not in the manufacture and distribution of them. Nor can there be any doubt that an inspector of the Food and Drug Administration was an employee within the meaning of the exemption, or that he was regularly and lawfully engaged in the transportation and/or storage of these drugs. As is well known, inspectors constantly transport and store such drugs as part of their regular duties."

Such an interpretation of Section 1.106(b)(1)(i)(a) is too strained to merit serious consideration. It would render futile the efforts of the Government to effectively investigate and prosecute violators. In construing the Food, Drug and Cosmetics Act the Court must be mindful of the purpose of Congress in enacting it. As the Court said in *United States* v. *Dotterweich,* 32 U.S. 277, at page 280,

> "[T]he purposes of this legislation thus touch phases of the life and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words".

See also *United States* vs. *Bodine,* 206 F. Supp. 201 and *United States* vs. *El-O-Pathic Pharmacy,* 192 F.2d 62, 75.

The defendant also urges that he has a good defense

since the deliveries involved in the charges were made in good faith, and cites Section 333(c) of said Title in support thereof. Clearly he does not come within the exceptions contained in that section, but even if "good faith" were available to him as a defense he waived it when, represented by counsel, he voluntarily pleaded guilty to the charges contained in counts 3 and 4.

As the Court said in *United States* vs. *Hohensee*, 243 F.2d 367, (cert. denied 353 U.S. 976, rehearing denied 354 U.S. 927),

> "[T]he Act imposes criminal sanctions as a means of regulating activities so dangerous to public welfare *as not to permit of exception for good faith or ignorance.*" (Emphasis supplied.)

Regardless of conscious fraud, anyone who shares in the responsibility of conducting a business operation which is violative of the Act commits an offense. *United States* vs. *48 jars, etc.*, 23 F.R.D. 192.

Counsel's claim under this Rule 32(d) motion "that the defendant was innocent, and . . . was ignorant at the time of pleading of defenses properly available to him . . ." falls far short of showing the "manifest injustice" required by the rule.

All the cases cited by counsel for the defendant in his memorandum and during the course of his oral argument are either inapposite or factually clearly distinguishable from the instant case.

Accordingly the motion is in all respects denied. Settle order on two days notice.

Dated: May 31, 1966.

LEO F. RAYFIEL
United States District Judge

APPENDIX D

Judgment of Court of Appeals

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals, in and for the Second Circuit, held at the United States Courthouse in the City of New York, on the Twenty-first day of October one thousand nine hundred and sixty-six.

Present:

HON. STERRY R. WATERMAN,
HON. PAUL R. HAYS,
HON. ROBERT P. ANDERSON,
Circuit Judges.

UNITED STATES OF AMERICA,
Plaintiff-Apellee,

v.

HENRY SCHEIN, doing business as Henry Schein,
Defendant-Appellant.

Appeal from the United States District Court for the Eastern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the

Judgment of Court of Appeals

Eastern District of New York, and was argued by counsel.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the order of said District Court be and it hereby is affirmed.

/s/ A. DANIEL FUSARO
Clerk

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